REMARKS

Applicants appreciate the thorough and detailed examination of the present application as evidenced by the Final Action dated August 22, 2006. Applicants further appreciate the indication that the claim rejections under 35 U.S.C. § 112 have been withdrawn and that the new title has been accepted. Applicants provide the comments below to address the issues presented in the Final Action and in support of the patentability of the pending claims.

As noted above, in the event that a Notice of Allowance is not issued in response hereto, the Examiner is respectfully requested to contact the undersigned in order to schedule an interview with Applicants and Applicants' representative.

I. Information Disclosure Statement

The Final Action asserts that the Information Disclosure Statements (IDS) other than the IDS dated 21 December 2004 are not considered in their entirety. As discussed with the Examiner during a teleconference on February 7, 2007, Patent No. 6,706,737 corresponds to the patent application of record. Applicants' representative further directed the Examiner's attention to the Manual of Patent Examining Procedure (M.P.E.P.) §609.02(A)(2), which states the following:

> **The examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under 37 CFR 1.53(b)** ** (B) a divisional application filed under **37 CFR 1.53(b)** ** or (C) a continuation-in-part application filed under 37 CFR 1.53(b). A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

M.P.E.P. §609.02(A)(2) (Emphasis added).

As previously noted, the IDS submitted by Applicants included a copy of a form PTO-1449 as filed in parent U.S. Patent Application Serial No. 10/434,259 with the Attorney Docket Number of the parent application struck through and the Attorney Docket number of the present application written thereon. Applicants further note that the references cited in the IDS filed in the present application appear on the face of the issued patent for the parent application, U.S. Patent No. 6,706,737. *See* attached pages 1-3 of the '737 patent.

Accordingly, Applicants reiterate its belief that the USPTO has previously received and/or reviewed the references cited in the IDS, and that Applicants are entitled to have the

references considered, and in the event of allowance, listed on a patent issuing from the present application.

II. Claims Rejections Under 35 U.S.C. § 102

Claims 65-84 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/32957 to Astra Aktiebolag (hereinafter, "Astra Aktiebolag"). *See* Final Action, page 3. More specifically, the Final Action asserts that "the WO 95/32957 reference does also teach optically pure forms of the active agent (see in particular lines 23-26 on page 3). Final Action, page 9.

Applicants respectfully submit that Astra Aktiebolag **does not** teach 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in pure form. Instead, on page 3, Astra Aktiebolag refers to **ethyl carbonate derivatives** (e.g. ethoxycarbonyloxymethyl derivatives) of omeprazole, which is a benzimidazole compound **substituted** with a carbonyldioxy moiety. On page 4, Astra Aktiebolag discusses single enantiomers of "omeprazole" noting that such compounds have, at that time, only been obtained as syrups and not as crystalline products. Notably, the structure shown is a 5-methoxy benzimidazole compound and not a 6-methoxy benzimidazole compound. Astra Aktiebolag proceeds to indicate that crystalline products can be obtained; however, the compounds obtained are described as pure regioisomers (as single structures or mixtures) specifically noted as N-ethoxycarbobonyloxymethyl derivatives, i.e., a 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-***1-ylmethyl ethyl carbonate*** isomer and a 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-***1-ylmethyl ethyl carbonate*** isomer. *See* page 4. Such compounds do not represent 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in pure form as recited in the pending claims.

"Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of ***each and every*** limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.,* 32 USPQ2d 1017, 1019 (Fed Cir. 1994) (Emphasis added).

Applicants respectfully submit that, as understood by those skilled in the art, the Astra Aktiebolag discussion of ethyl carbonate derivatives (e.g. **substituted, ethoxycarbonyloxymethyl derivatives**) of omeprazole, with specific focus on the 5-

methoxy compound, does not teach or suggest 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in pure form.

Accordingly, Applicants respectfully submit that Claims 65-84 are not anticipated by Astra Aktiebolag, and Applicants respectfully request that this rejection be withdrawn.

V. Nonstatutory Double Patenting Rejection

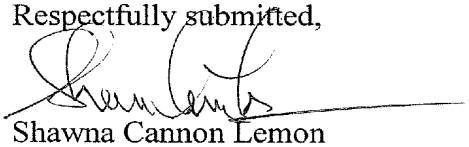
Applicants reiterate the intention to submit a terminal disclaimer upon indication that the pending claims are allowed. Again, Applicants' offer to submit the terminal disclaimer should not be construed as an admission with respect to the nonstatutory double patenting rejections or the Examiner's characterization of Applicants' cited patents as set forth in the previous Office Action.

Conclusion

At least in view of the foregoing remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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US006706737B2

(12) **United States Patent**
Whittle et al.

(10) **Patent No.: US 6,706,737 B2**
(45) **Date of Patent: *Mar. 16, 2004**

(54) **ALKOXY SUBSTITUTED BENZIMIDAZOLE COMPOUNDS, PHARMACEUTICAL PREPARATIONS CONTAINING THE SAME, AND METHODS OF USING THE SAME**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/434,259**

(22) Filed: **May 8, 2003**

(65) **Prior Publication Data**

US 2003/0225136 A1 Dec. 4, 2003

Related U.S. Application Data

(63) Continuation of application No. 10/189,659, filed on Jul. 3, 2002, which is a continuation of application No. 10/057,659, filed on Jan. 25, 2002, now Pat. No. 6,444,689, which is a continuation of application No. 09/645,145, filed on Aug. 24, 2000, now Pat. No. 6,369,087, which is a continuation-in-part of application No. 09/519,976, filed on Mar. 7, 2000, now Pat. No. 6,262,085.

(60) Provisional application No. 60/150,878, filed on Aug. 26, 1999.

(51) **Int. Cl.**[7] **A61K 31/44**

(52) **U.S. Cl.** **514/338**

(58) **Field of Search** 514/338

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(57) **ABSTRACT**

Compounds represented by formula (Ia) are disclosed by the invention, along with compositions and complexes thereof, optionally in combination with compounds of formula (Ib). Pharmaceutical formulations and methods of making and using such compounds are also disclosed.

17 Claims, No Drawings

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